Pragmatic Research with Real-World Clinical and Community Settings: Challenges, Opportunities, and Recommendations for Success

Monday, May 24, 2021 | 11:15 AM

COPRH Con

Colorado Pragmatic Research in Health Conference

ACCORDS
UNIVERSITY OF COLORADO
CHILDREN'S HOSPITAL COLORADO

Colorado Clinical and Translational Sciences Institute (CCTSI)
UNIVERSITY OF COLORADO DENVER | ANSCHUTZ MEDICAL CAMPUS

The Substance Abuse Treatment to HIV Care (SAT2HIV) Project: An example of a completed dual-randomized type 2 hybrid trial

Presented by:
Bryan R. Garner, PhD
Senior Implementation Research Scientist
RTI International
3040 E. Cornwallis Rd.
Research Triangle Park, NC 27709
Phone: (919) 597-5159
Email: bgarner@rti.org

Funding provided by the National Institute on Drug Abuse
(NIDA; R01-DA038146; PI: Garner)

RTI INTERNATIONAL
www.rti.org

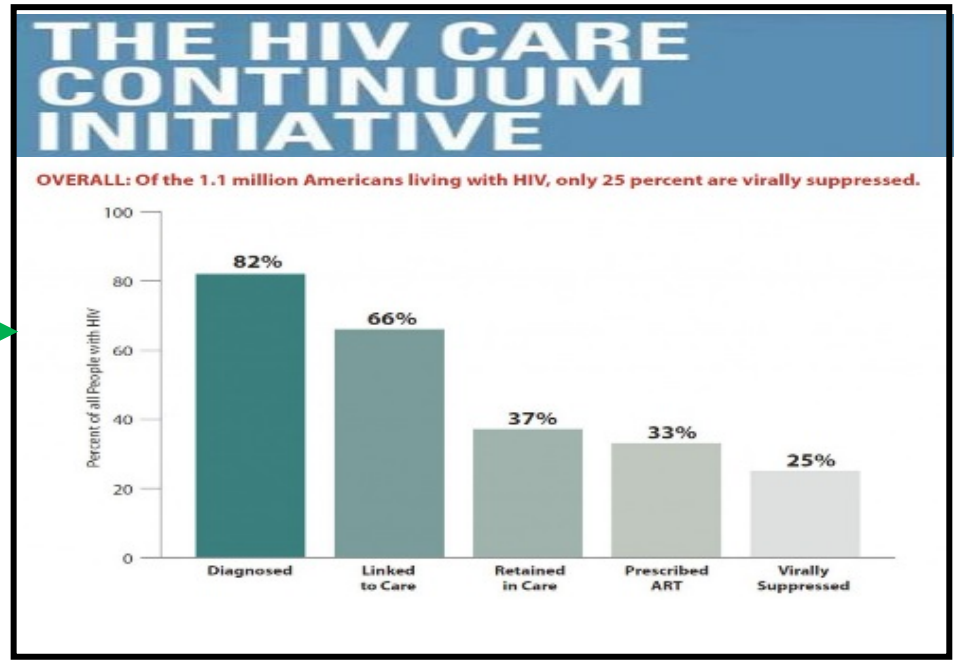
SAT2HIV
FUNDED BY THE NATIONAL INSTITUTE ON DRUG ABUSE
www.SAT2HIV.org

ISF
IMPLEMENTATION & SUSTAINMENT FACILITATION
www.ISFstrategy.org

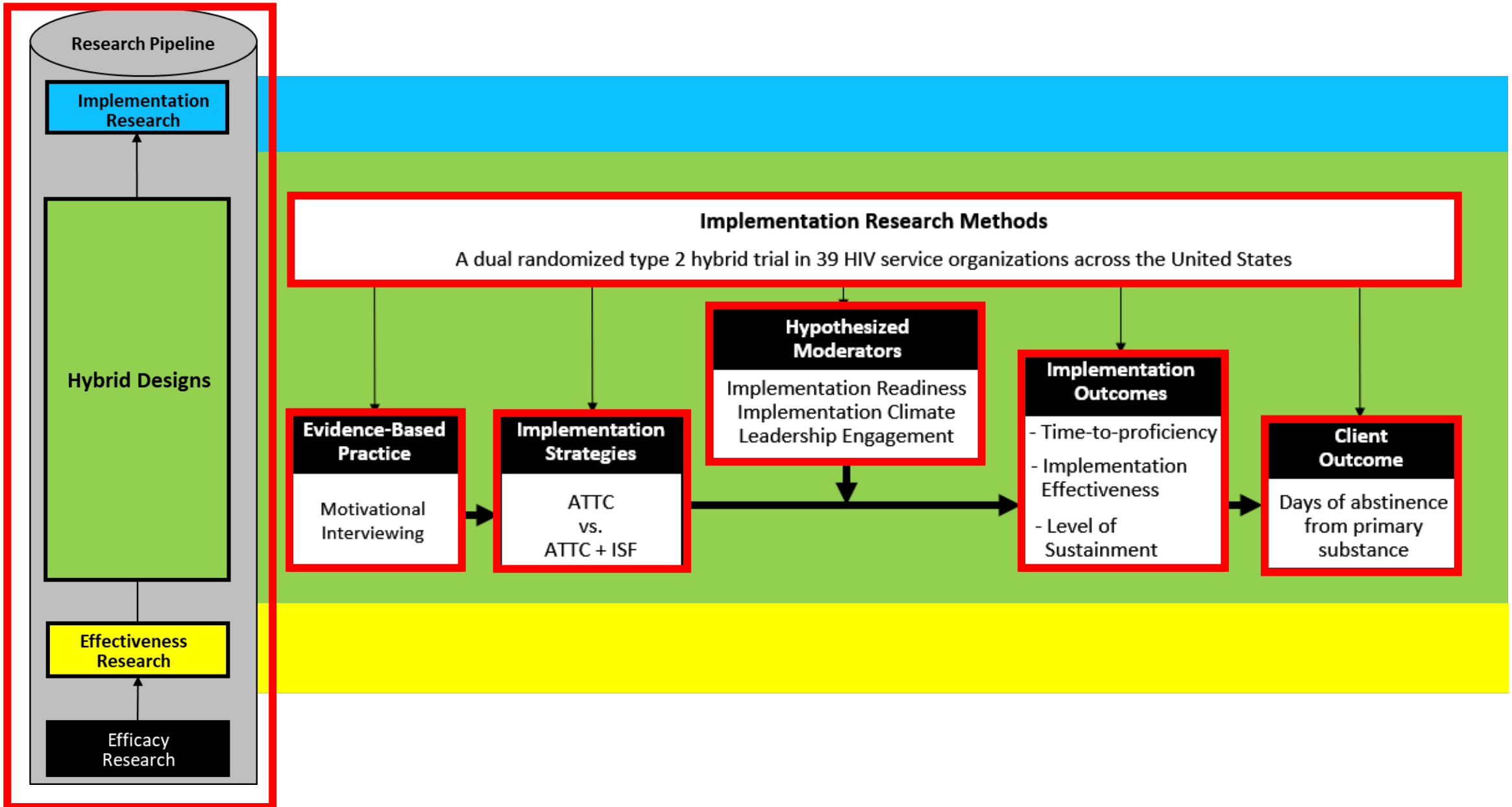
The Setting and Public Health Issues

Substance use can <u>negatively impact</u> ASOs ability to achieve goals of the HIV Care Continuum

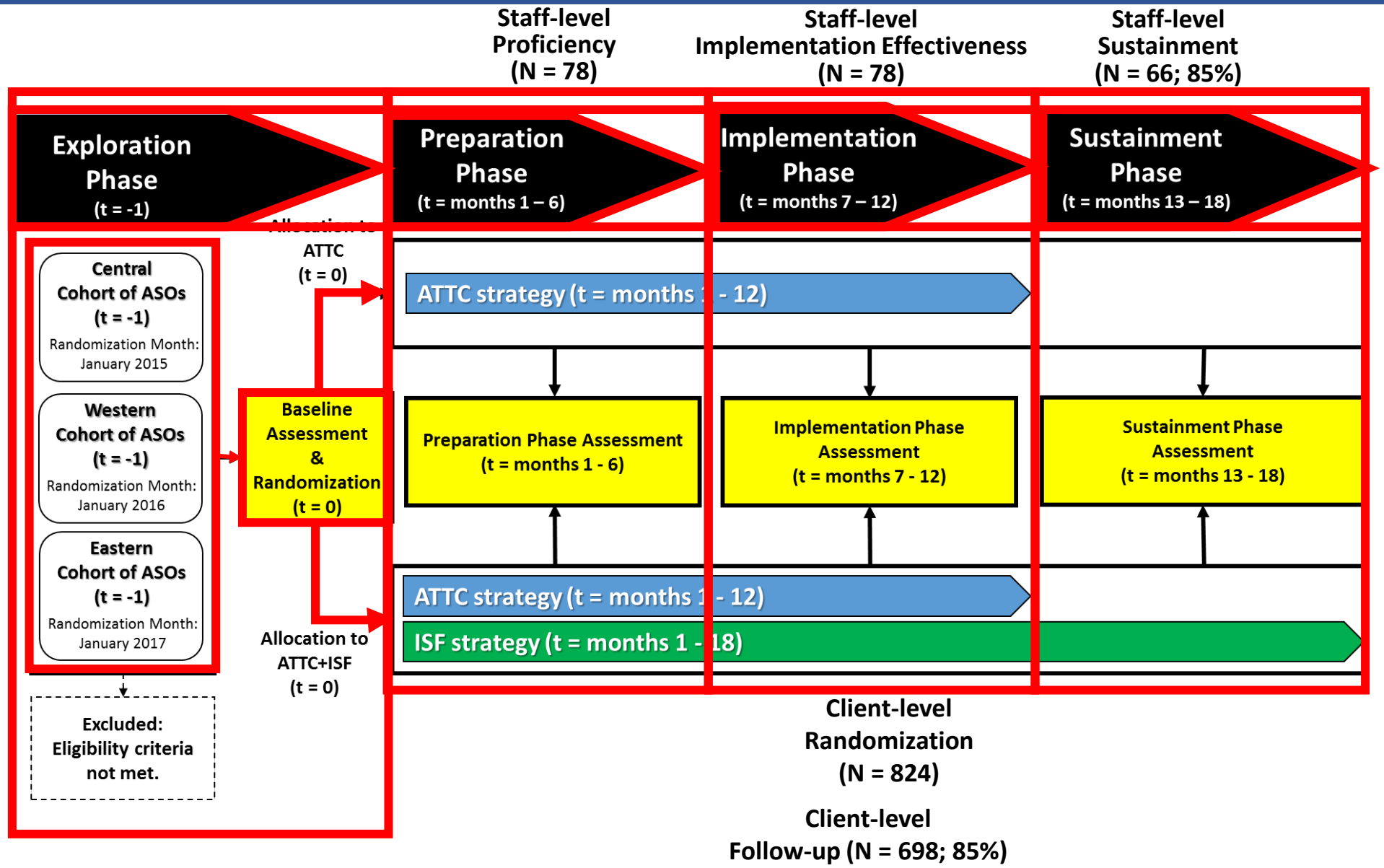
AIDS SERVICE ORGANIZATIONS



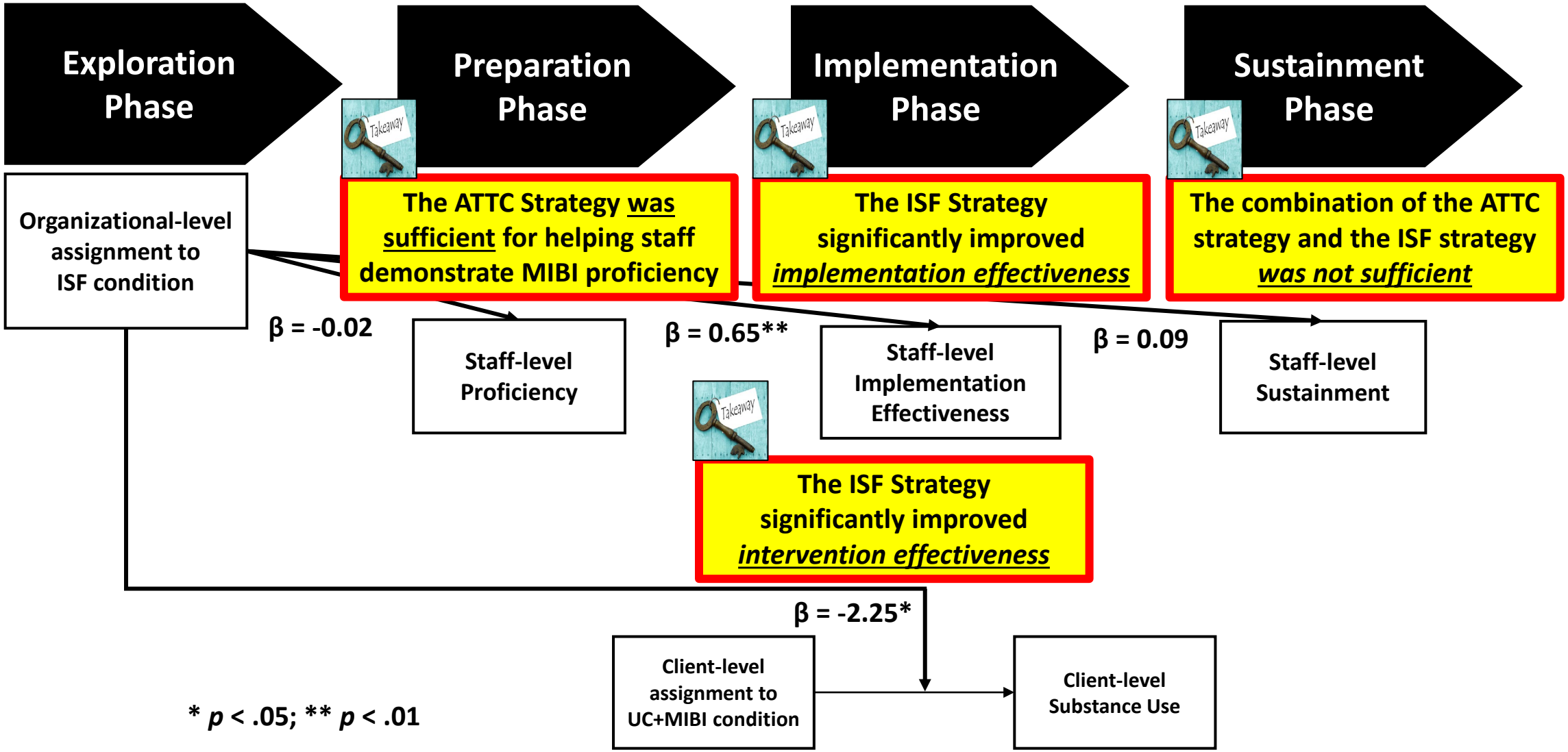
The SAT2HIV Project's Conceptual Model



The SAT2HIV Project's Flow Diagram



The SAT2HIV Project's Key Findings (Garner et al., 2020)



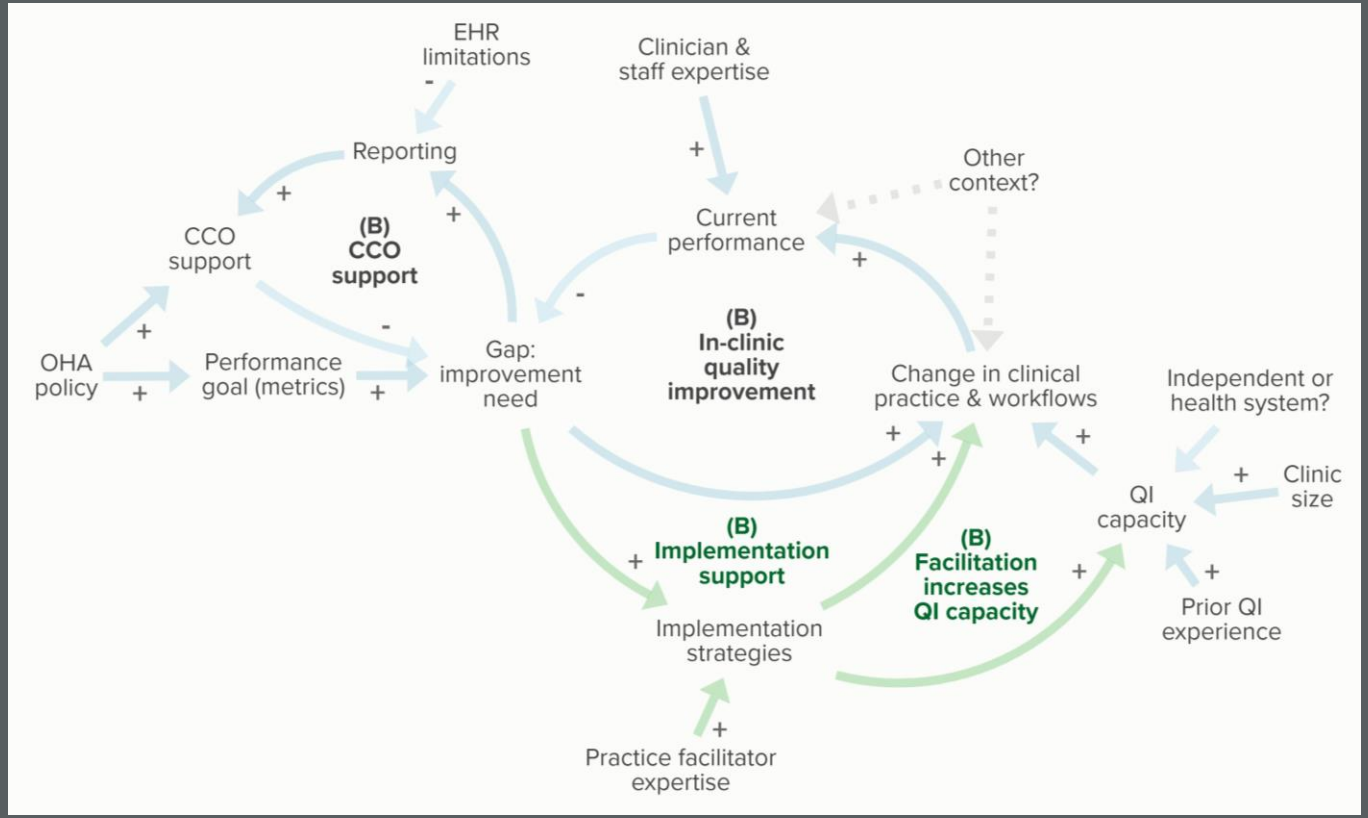
Combining qualitative interviewing with systems science to understand how practice facilitators tailor implementation support to context

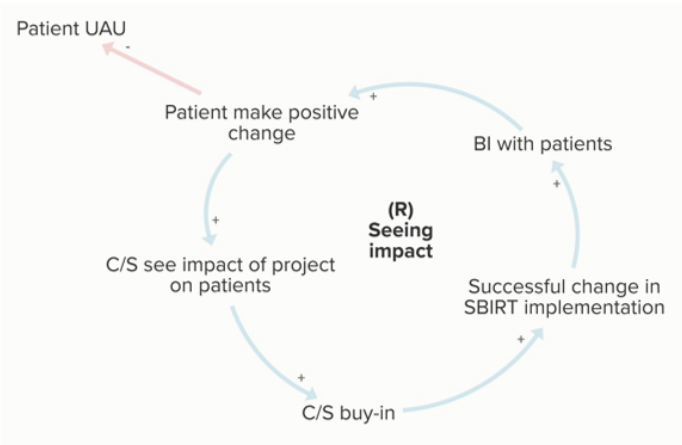
Erin Kenzie, PhD; Emily Myers, BS; Caitlin Dickinson, MPH; Melinda Davis, PhD
Oregon Rural Practice-based Research Network
Oregon Health & Science University
March 24, 2021

ANTECEDENT

- How do practice facilitators tailor implementation support based on context, intervention, and personal expertise?
- What are practice facilitators' mental models of practice change?

Causal-loop diagramming

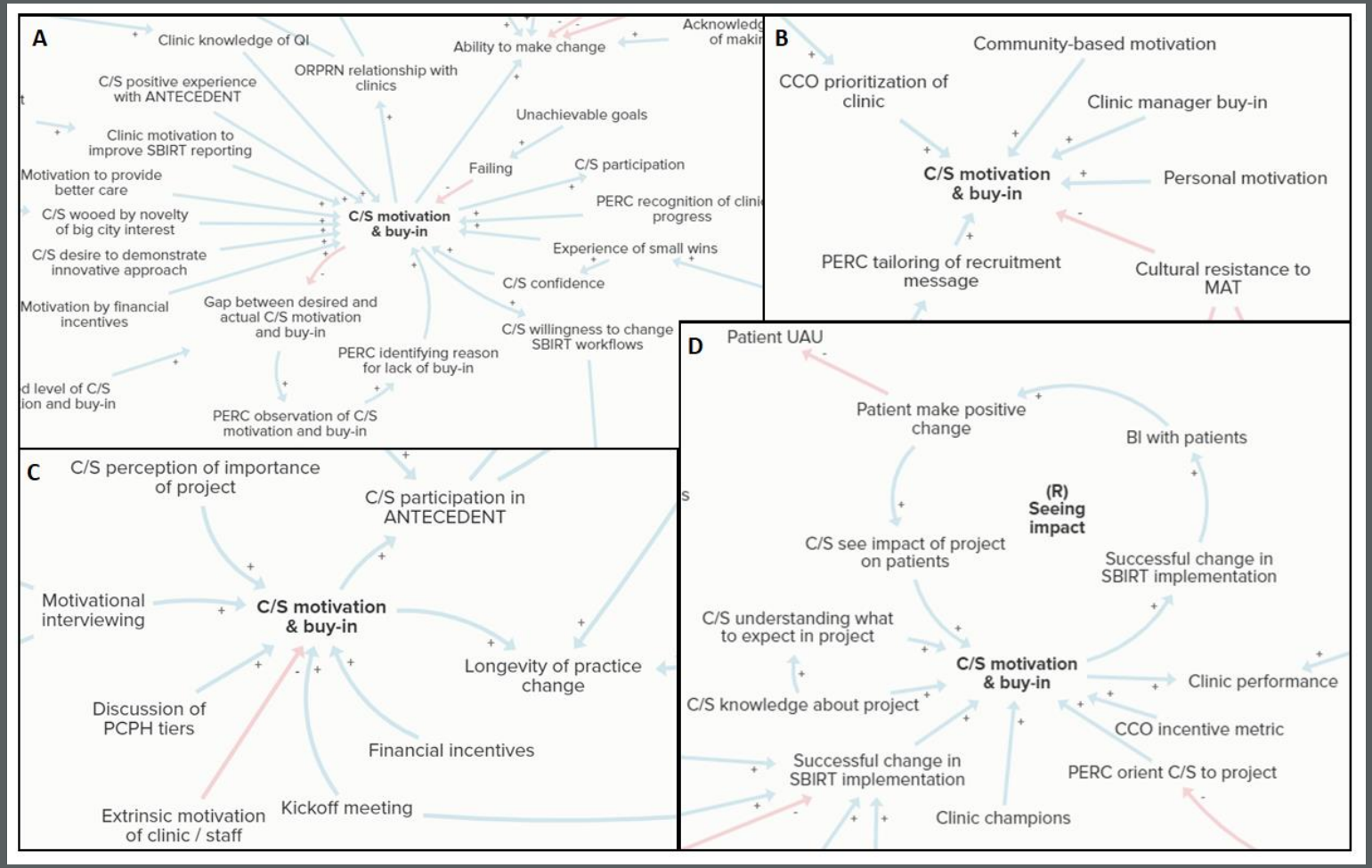


Quotation:	**Interviewer:** I'm wondering about change in the long-term. Not just signing up or making some changes initially, but what helps clinics be successful in the long-term and really make that sustainable? **Interviewee 5:** Well, not to sound like a broken record, but I think that having that buy-in is obviously really important and I think for the clinics to be able to see how this impacts their patients positively is really important. So, seeing some results, seeing the benefits of a patient that's been offered a brief intervention and takes that to heart and does decide to make some changes or do whatever is a good next step for them. I think that those are the aspects that might sustain that change and encourage the clinics. So, I think seeing those results is going to be a strong or a big motivator for the clinics in implementing the work and being motivated to sustain that.
Code:	Causal_feedback loops
Comment:	C/S buy-in building over time C/S see impact of project on patients —> C/S buy-in —> Successful change in long term SBIRT performance —> BI with patients —> patients make positive change —> C/S see impact . . . (reinforcing loop)
Diagram:	

From qualitative data to diagram

Kenzie, Erin Suzanne, "Get Your Model Out There: Advancing Methods for Developing and Using Causal-Loop Diagrams" (2021). Dissertations and Theses. Paper 5664.
https://doi.org/10.15760/etd.7536

OHSU



Kenzie, Erin Suzanne, "Get Your Model Out There: Advancing Methods for Developing and Using Causal-Loop Diagrams" (2021). Dissertations and Theses. Paper 5664. https://doi.org/10.15760/etd.7536

Strengths of approach

- New way of analyzing and communicating qualitative information
- Facilitates comparison of individuals' mental models and change over time
- Can be applied to stakeholder interview data
- Increases access compared to standard group modeling

Limitations of approach

- Requires expertise in causal-loop diagramming and qualitative analysis
- Time consuming

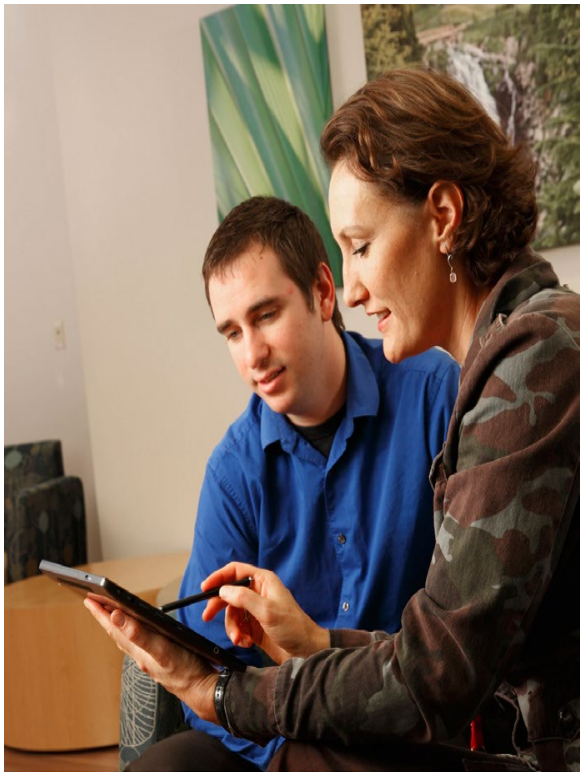
OHSU

Adaptation of a Quality Improvement Approach to Implement eSceening in VHA Healthcare Settings

James O. E. Pittman, PhD, LCSW, Borsika Rabin, MPH, PhD, PharmD, Erin Almklov, PhD, Niloofar Afari, PhD, Elizabeth Floto, MS, Eusebio Rodriguez, MBA, Laurie Lindamer, PhD.

- The Veterans Health Administration (VHA) developed a comprehensive mobile screening technology (eScreening) that provides customized and automated self-report health screening via mobile tablet for veterans seen in VHA settings.

- We needed a strategy for scale-up of eScreening
  - » Quality improvement (QI) methods may offer solutions to overcome barriers related to broad scale implementation of technology in health systems.



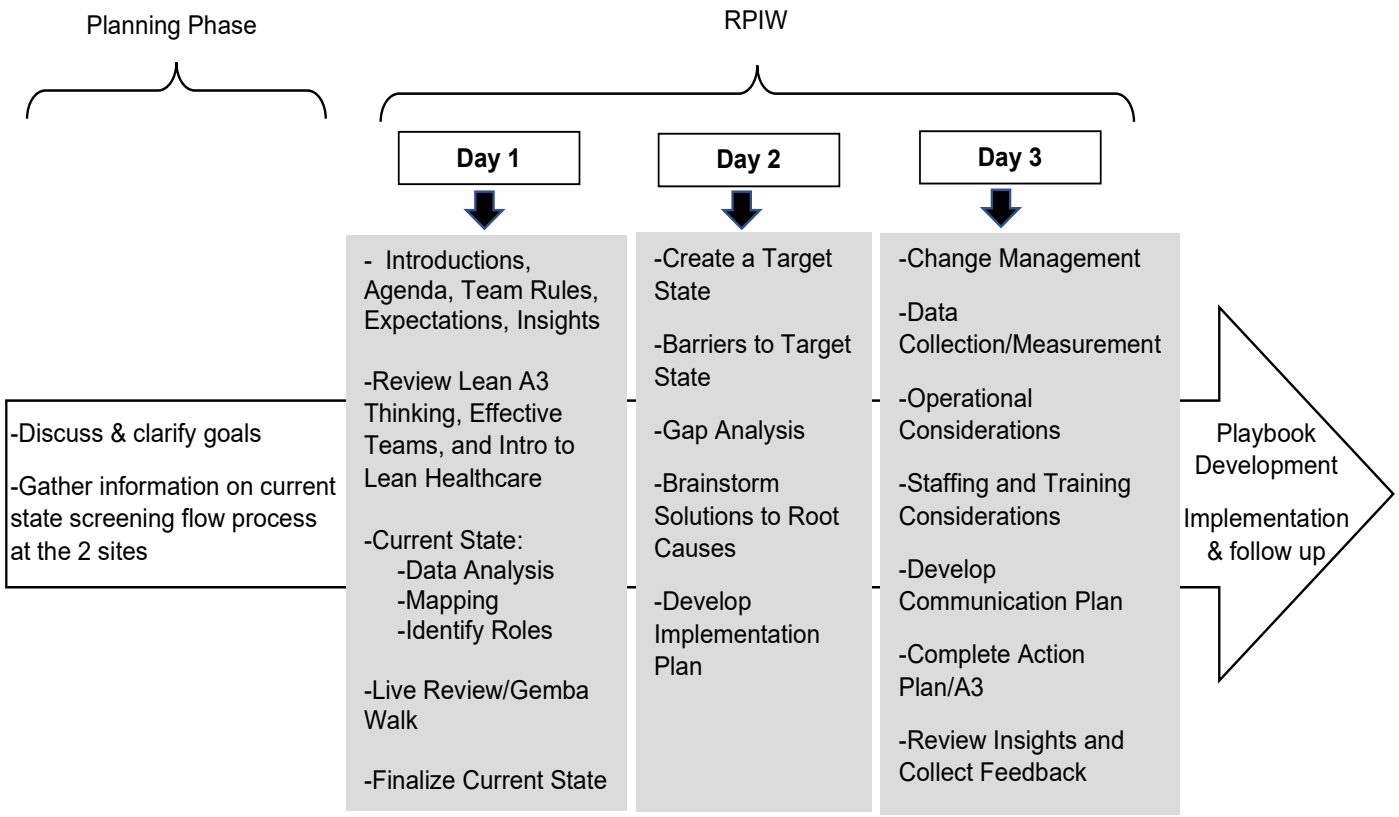
VA CENTER OF EXCELLENCE CESAMH STRESS AND MENTAL HEALTH

UCSD

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Methods (Phase 1)

Adapted Rapid Process Improvement Workshop (RPIW)



VA CENTER OF EXCELLENCE CESAMH STRESS AND MENTAL HEALTH

UCSD

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Methods (Phase 2)

- Sites
- Data
  - » Complementary Mixed methods
    - eScreening Pre-implementation Survey data
    - Implementation Process Mini Interviews
- Analyses
  - » Quantitative
  - » Qualitative

Results

Quantitative

- Both sites' staff provided positive responses on the survey related to eScreening, but some differential trends emerged:
  - » Site 1 had more agreement about the specific roles related to eScreening and its compatibility with workflow and resources than site 2.
  - » Site 2 reported more leadership support and role communication than site 1.

Qualitative

Challenges:

- IT Support
- Educational
- Workflow/staffing

Conclusions

- A RPIW can be an important factor in the adoption of health technology, but organizational factors also need to be addressed.
- Successful adoption of health technology needs to be flexible and contain multiple components.
- Our use of RPIW and other QI methods to both develop a playbook and an implementation strategy for eScreening has created a testable implementation process to employ automated, patient-facing assessment.
- The efficient collection and communication of patient information has the potential to greatly improve access to and quality of healthcare.

SHARE TRUST ORGANIZE PARTNER STOP COVID-19 CA

THE COVID-19 CALIFORNIA ALLIANCE

Partnering Community Organizations, Stakeholders, and Individuals from across California with: UCLA • SDSU • Scripps Stanford • UCD • UCI • UCM • UCR • UCSD • UCSF • USC

CO-CREATE

Using Meaningful Community Engagement Methods to Advance COVID-19 Testing and Vaccine Uptake in Underserved Communities

Nicole Stadnick, Kelli Cain, William Oswald, Paul Watson, Marina Castelo, Raphael Logoc, Lawrence Ayers, Linda Salgin, Shelia Broyles, Louise C. Laurent, Borsika Rabin

UC San Diego | ACTRI Dissemination & Implementation Science Center | San Ysidro Health | The Global Action Research Center

Colorado Pragmatic Research in Health Conference 2021

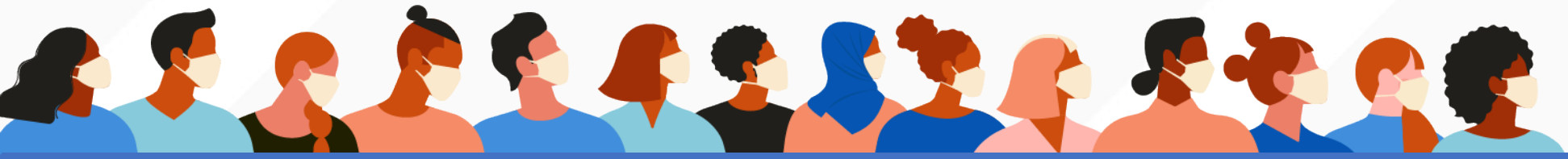
Strategies for Community Engagement

STOP COVID-19 CA

- Community Advisory Board with diverse representation of community and policymakers
  - Theory of Change ☑
  - Appreciative Inquiry
- Survey (n=100) in multiple languages (English, Spanish, Arabic, Somali, Swahili, Kizagua +?)—*in process*
- Listening sessions (n=20) in multiple languages (English, Spanish, Arabic)-*in process*

CO-CREATE

- Community and Scientific Advisory Board with diverse representation of community, health clinic partner, and public health researchers
  - Theory of Change ☑
  - Appreciative Inquiry
- Survey in Spanish and English
  - n=18 providers
  - n=162 patients, caregivers, supporters
- Brainwriting exercise of testing program in Spanish and English—*in process*



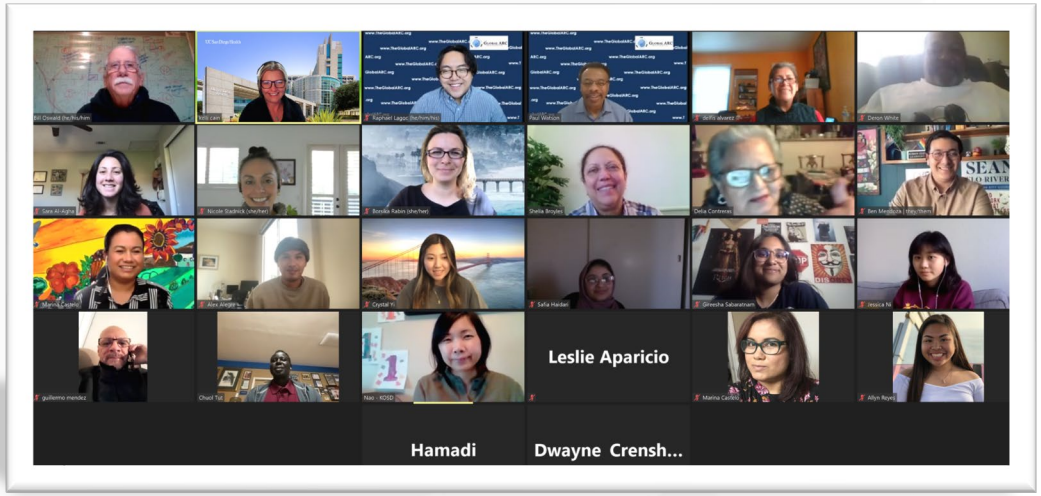
NIH National Institutes of Health

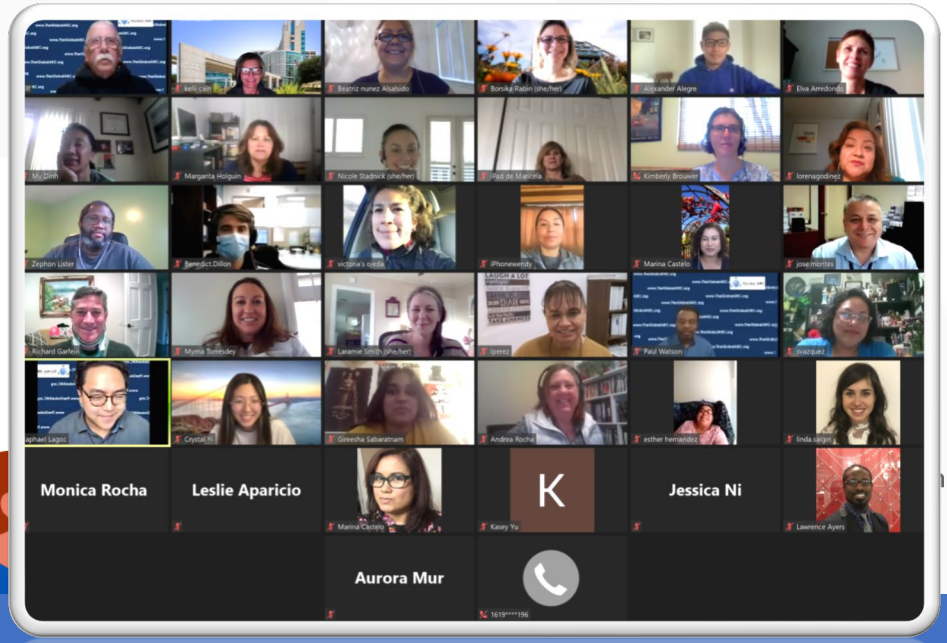
Community Advisory Board Meetings

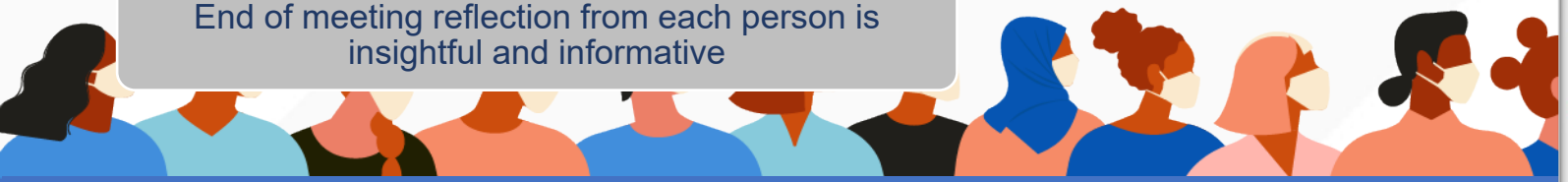
- **33 CAB members + 2 policy partners**
- **A total of 15 meetings completed**
- **Zoom, breakout rooms, Miro boards, live interpretation**

Lessons learned:

- Translate all materials
- Speak slowly, take breaks for interpretation
- Technology assistance (devices, internet, ongoing assistance)
- 4:30-6:30pm works well
- 2 scribes/facilitators in each breakout room
- End of meeting reflection from each person is insightful and informative

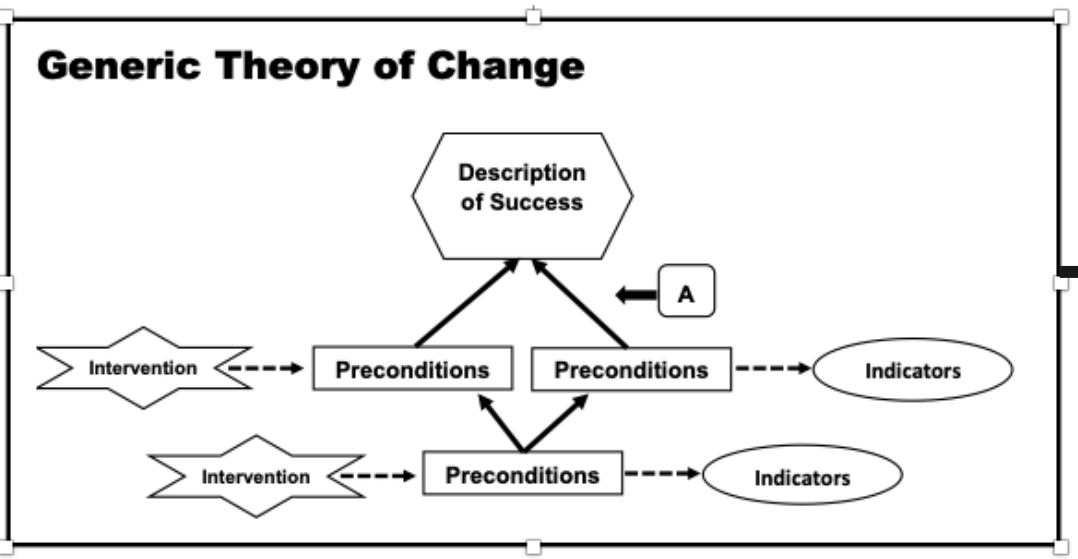


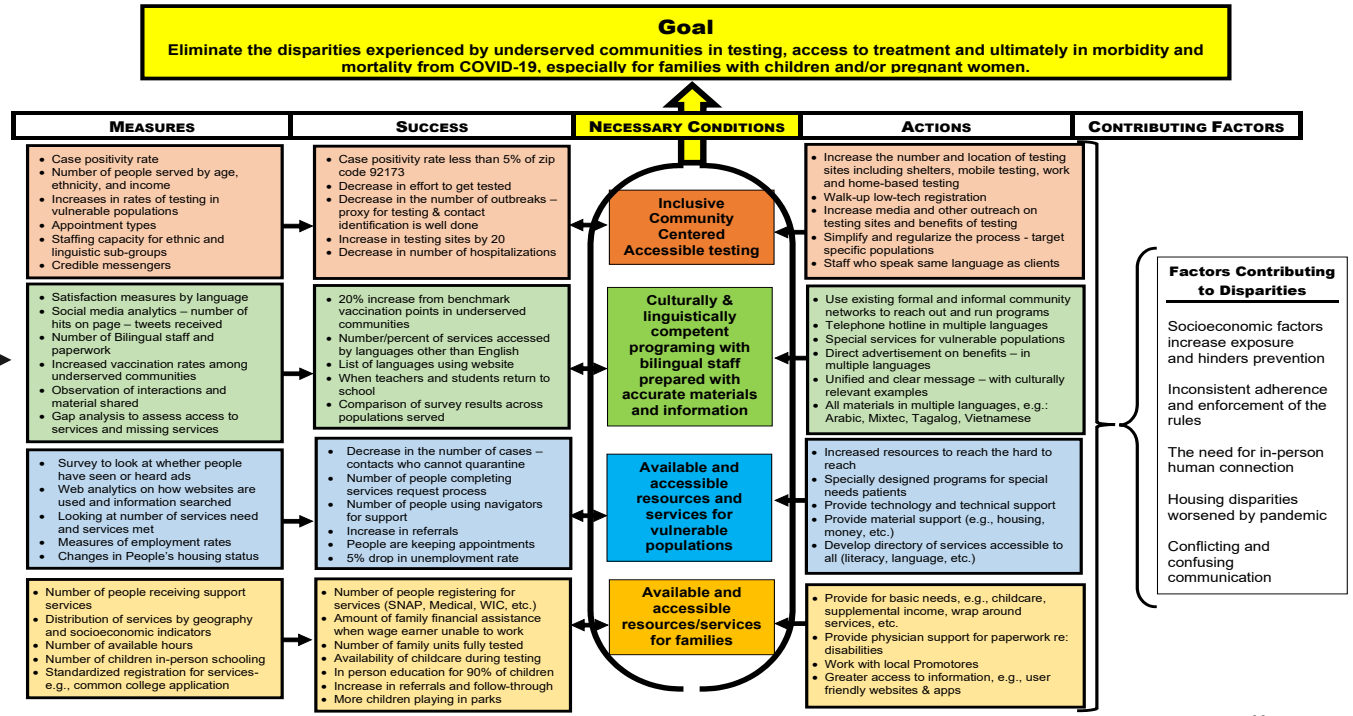




Theory of Change (ToC)

- Comprehensive description and illustration of how and why a desired change is expected to happen in a particular context
- ‘Logic model on steroids’
- CABs completed a ToC, focused on identifying necessary conditions for equitable COVID-19 testing and vaccination, actions to create those conditions, and a blueprint for assessing efficacy

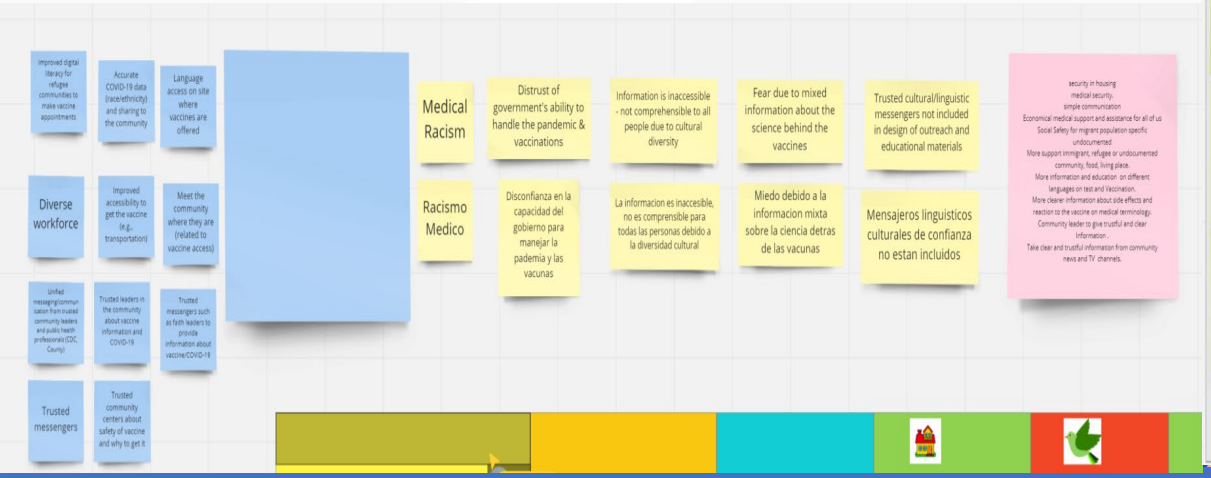




(https://www.theoryofchange.org/what-is-theory-of-change/)

Theory of Change – 6 sessions

- Each session guided by a 1) focus question, 2) ideas generated, 3) sorted into categories, 4) categories named, and 5) ranked in order of importance
  - Contributing Factors
  - Necessary Conditions
  - Actions
  - Indicators of Success



Thank You!

	STOP COVID-19 CA	CO-CREATE
PIs	Borsika Rabin, Nicole Stadnick	Robert Tukey, Louise Laurent, Jeannette Aldous
Co-Is	Paul Watson, Bill Oswald, Shelia Broyles, Gregory Aarons, Lauren Brookman-Frazee, Jesse Nodora, Bonnie Kaiser	Borsika Rabin, Nicole Stadnick, Paul Watson, Bill Oswald, Marva Seifert, Keith Pezzoli, Ilya Zaslavsky, Fatima Munoz, Timothy Sahms, My Dinh, Rob Knight, Gene Yeo
Project managers & staff	Kelli Cain, Marina Castelo, Raphael Lagoc	Kelli Cain, Linda Salgin, Andrea Svoboda, Marina Castelo, Raphael Lagoc, Shashank Sathe, David Valentine, Nikol Sarbaich
CRCs		Lawrence Ayers, Maria Linda Burola, Anne-Marie Engler, Luis Gay, Alexis Osuna
Interns	Jillian Abasta, Nicholas Lee, Allyn Reyes, Crystal Yi, Leslie Aparicio, Gireesha Sabaratnam, Alex Alegre, Jessica Ni	Ariel Cohen, Jillian Abasta, Nicholas Lee, Allyn Reyes, Crystal Yi, Leslie Aparicio, Gireesha Sabaratnam, Alex Alegre, Jessica Ni, Kasey Yu, Arleth Escoto, Angela Pham, Clara Laurent, Dan Maunder, Eli Lawrence
Funding sources	National Institutes of Health OTA-21-312-0217571-66106L (CEAL)	National Institutes of Health P42 ES010337-19S2 (RADx-UP Supplement)

NIH National Institutes of Health

Prevalence and factors associated with patient-reported outcomes in pragmatic randomized controlled trials

Shelley Vanderhout, PhD, RD

Colorado Pragmatic Research in Health Conference
May 24 2021

uOttawa

Background & Objectives

Background

- Pragmatic randomized controlled trials (RCTs) are intended to guide clinical decision making by studying interventions and patient-important outcomes in usual care settings

- Patient-reported outcomes (PROs) are subjective measures of health that come directly from patients, without interpretation by clinicians or anyone else

- PROs are considered patient-centred and well suited to pragmatic trials, but their use and reporting in pragmatic trials has not been described

Objectives

Among health-focused pragmatic RCTs, to determine:

1. The prevalence and types of PROs used.

2. Factors associated with the use of PROs as primary/co-primary outcomes.

Methods

Search

- An electronic search filter was developed and applied to MEDLINE to identify primary reports of health-focused pragmatic RCTs published 2014-2019 and registered at ClinicalTrials.gov

Extraction

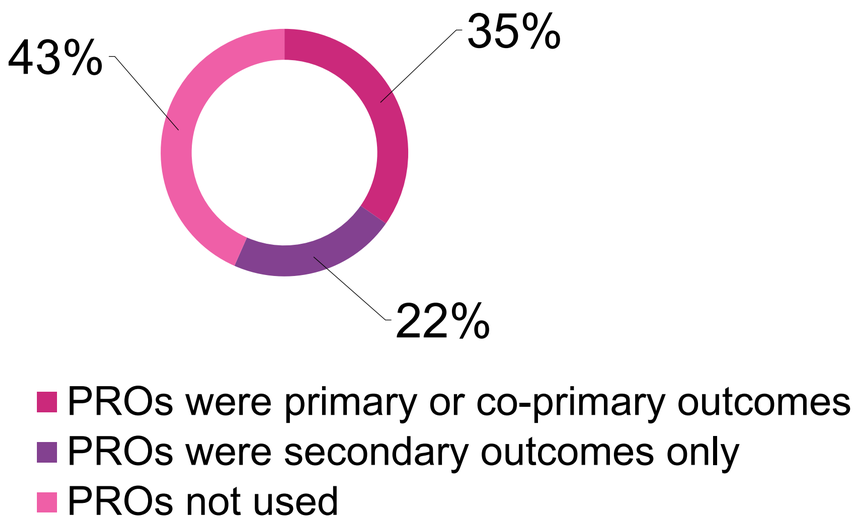
- Trial descriptors were downloaded from ClinicalTrials.gov and extracted manually

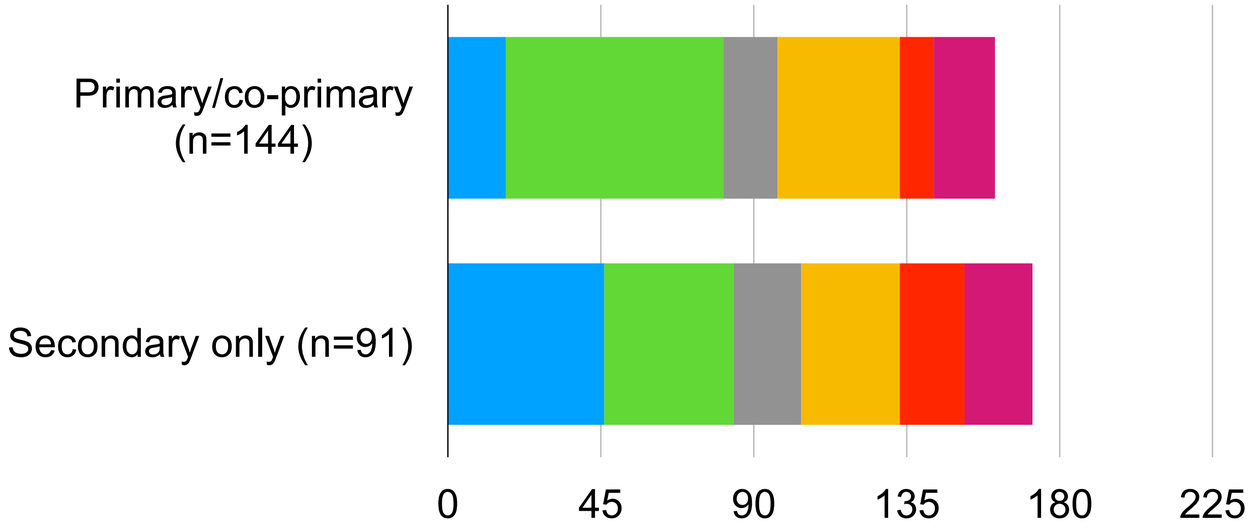
Analysis

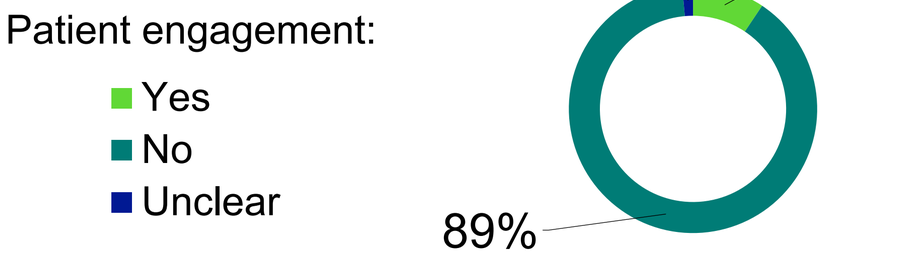
- Descriptive statistics were used to summarize trial characteristics
- Chi-squared, Wilcoxon rank sum, and Cochran-Armitage trend tests were used to compare characteristics of trials with and without PROs as primary outcomes

Results

415 trials met inclusion criteria:







Note: multiple selections per trial were possible. QOL = Quality of Life. HRQOL = Health-Related Quality of Life.

Results

Factors associated with use of PROs as primary/co-primary outcomes

Higher prevalence	Lower prevalence	Not associated
Conducted in Europe vs. elsewhere	Published in higher impact journals	Patient/stakeholder engagement
Primary purpose was treatment vs. prevention, health services research, other	Conducted in low- or middle-income countries vs. elsewhere	Clinical setting vs. non-clinical
Dietary or behavioural interventions vs. clinical, other	Paediatric or older adult participants vs. all ages	Year of publication
Individually randomized vs. cluster	Industry funded vs. government, university, foundation, other	Government, university or foundation funded vs. industry, other

Discussion & Implications

- PROs were infrequently used in pragmatic trials
- Patient and stakeholder engagement was rare
- Individually (vs. cluster) randomized studies, those conducted in Europe, and dietary or behavioural interventions were more likely to use PROs
- Studies published in higher impact journals or funded by industry were less likely to use PROs
- Research funding bodies, institutions and scientific journals can support the use of PROs and patient engagement in pragmatic trials by establishing policies, providing methodological support, or creating incentives

Acknowledgements

- Dr. Monica Taljaard, Dr. Jonathan Cook, Dr. Dean Fergusson
- Alison Howie, Kelly Carroll, Dr. Stuart Nicholls, Hayden Nix, Natalie Nightingale, Dr. Merrick Zwarenstein, Paxton Montgomery Moon

CIHR IRSC
Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

Wrap up

ACCORDS

COPRH Con

Colorado Pragmatic Research in Health Conference

THANK YOU!

ACCORDS
UNIVERSITY OF COLORADO
CHILDREN'S HOSPITAL COLORADO

Colorado Clinical and Translational Sciences Institute (CCTSI)
UNIVERSITY OF COLORADO **DENVER | ANSCHUTZ MEDICAL CAMPUS**